Practical Pointers for Conducting Commercial Sector Family Planning Regulatory Assessments

by

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The PROFIT (Promoting Financial Investments and Transfers) Project seeks to mobilize the resources of the commercial sector to expand and improve the delivery of family planning services in selected developing countries. The PROFIT Project is a consortium of five firms, led by the international management consulting firm of Deloitte Touche Tohmatsu and including the Boston University Center for International Health, Multinational Strategies, Inc., Development Associates, Inc., and Family Health International.

This report is part of a series of PROFIT Research Studies, which address various topics related to private sector family planning. The studies grow out of PROFIT subprojects within the following three strategic areas: innovative investments, private health care providers, and employer-provided services.

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ABSTRACT

Regulatory reform can be a critical component of efforts to increase the commercial sector's role in delivering family planning services, but no single strategy will work in every country. A thorough regulatory assessment will help identify which strategies will be most appropriate. Such an assessment should examine five areas: regulations that constrain contraceptive options; tax and import policies; advertising and promotion regulations; other regulations that affect the commercial sector; and restrictions on nonprofit organizations. PROFIT's experience provides three lessons for conducting a regulatory assessment. First, develop a clear understanding of what existing regulations say and what they do not say. Second, look beyond the written laws and regulations to understand how they are actually implemented and practiced. Finally, determine whether regulatory reform can have a meaningful effect on the commercial sector role in family planning by carefully studying existing patterns of contraceptive provision and use and relating them to the existing regulatory structure.

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ACRONYMS

DHS	Demographic and Health Survey
IDS	Intercensal Demographic Survey, Vietnam
IMCC	Institute for Mother and Child Care, Romania
MOH	Ministry of Health
NGO	Nongovernmental organizations
PROFIT	Promoting Financial Investments and Transfers Project
USAID	U.S. Agency for International Development

EXECUTIVE SUMMARY

Since 1992, the Promoting Financial Investments and Transfers (PROFIT) Project, sponsored by the U.S. Agency for International Development (USAID), has been working to expand the commercial sector provision of family planning services in developing countries. PROFIT has explored a wide variety of potential subprojects which have included conducting regulatory assessments in each potential host country. As part of its efforts to expand commercial sector provision of family planning services in developing countries, the PROFIT Project has assessed the feasibility of a wide variety of potential subprojects. Part of this assessment process is a review of the regulatory environment in each potential host country.

Regulatory reform is an important component of efforts to increase the commercial sector's role in delivering family planning services, but no single strategy will work in every country. A thorough regulatory assessment will help to determine which strategies will be most appropriate. For example, one strategy may be to open a dialogue among representatives of the commercial family planning sector and public health officials in order to identify barriers to increased commercial sector involvement in family planning and to attempt to reduce or eliminate them. Another strategy may be to aggressively lobby the government to eliminate regulatory barriers to effective delivery of family planning, such as import taxes on contraceptive commodities or regulations that restrict the ability of health care professionals to provide services. A third strategy may be to creatively work around the regulatory barriers in a particular environment.

Regulatory assessments should include five components:

- regulations that constrain contraceptive options
- tax and import policies
- advertising and promotion regulations
- other regulations that affect the commercial sector
- restrictions on nonprofit organizations

Practical Tips

- Whenever your analysis points to a relevant regulation, get a copy and have it translated independently. Careful study of the text may suggest that the laws and regulations provide more or less flexibility than is exercised administratively.
- Use consistent questions with flexible follow-up across all the sources interviewed. Interviews must be designed to get consistent information, but the interviewer must respond promptly to statements that suggest inconsistencies or identify previously unrecognized requirements. Start with a list of questions, and try to cover all of them in the interview.
- Document interview notes promptly. When your team splits up to interview different parties, the notes provide a way to share experiences. The notes also become the most important source for assembling recommendations and preparing a final report.
- Assess the impact of regulatory reform on providers based on the number and type of providers who would be affected. The importance of a particular regulation depends on the number of providers subject to it. However, it is difficult to get accurate estimates of the number of private providers within a particular category broken down by geographic location, and you may need to use two or three estimating techniques.
- Determine the licensing standards used for nonprofit and nongovernmental organization clinics. Regulatory policies can constrain the ability of nonprofit organizations to provide family planning services, because these organizations are generally held to the same licensing standards as for-profit clinics or pharmacies. Explore with the regulators whether there is a possibility of granting exceptions to well-funded and well-managed nonprofit clinics. It is also important to determine if nonprofit organizations are treated differently under the laws governing corporate formation or taxation.
- Search for and understand the ramifications of unwritten, informal regulations. It is important to learn as much as possible about the standards actually used in inspections. If possible, accompany an inspector, or look at reports citing regulatory violations. It may be helpful to encourage the country to analyze the costs and benefits of such de facto standards and to explore whether a more lenient, alternative standard would

provide an acceptable level of quality. If, as in some countries, the discretion left to inspectors is an invitation to corruption, then it may be necessary to consider including a revised and reasonable standard in written regulations.

Consider the commercial needs of the private sector as you analyze regulations. It is important to understand the economic forces that drive the commercial sector and to suggest reforms that are consistent with these economic forces. Attempts to craft regulations that respect the economic realities facing commercial practices can improve providers' willingness to expand family planning services.

Understand the ramifications of tax and trade barriers at the retail level. Importers and distributors are usually well-versed in current tax and trade issues. Determine the existing, as well as the historic effect of such barriers, including price controls and the effect of foreign exchange.

Identify hidden advertising and promotion regulations. Advertising and promotion regulations are often not well documented or stipulated. Even private media outlets may have unwritten policies about sensitive subjects such as contraception that reflect the opinions of the owners, advertisers, or readers. The best way to identify these unwritten policies is to talk to advertisers and advertising agencies about the problems they have faced in placing advertisements or public relations materials.

Seek information from multiple perspectives. Laws may be written, but the implementing regulations may never be issued or may be enforced unevenly. Even where regulatory language appears explicit, there is often substantial room for administrative interpretation. It is important to understand the real regulatory climate faced by individuals or companies in the commodity production/distribution chain and in the provision of family planning services.

Factor family planning survey data into the regulatory analysis. Review the most recent surveys of family planning practices, including the DHS (Demographic and Health Survey). These data should not only show the level of contraceptive knowledge and prevalence, but the current sources of supply for contraceptive users.

Conclusions

Regulatory reform is an important component of efforts to increase the commercial sector's role in delivering family planning services, but no single strategy will work in every country. A thorough regulatory assessment will help to determine which strategies will be most appropriate. PROFIT's experience provides three lessons for conducting this type of assessment:

- Develop a clear understanding of what existing regulations do and do not say.
- Look beyond the written laws and regulations to understand how they are actually implemented and practiced.
- Determine whether regulatory reform can have a meaningful effect on the commercial sector role in family planning by carefully studying existing patterns of contraceptive provision and use and relating them to the existing regulatory structure.

1.0 INTRODUCTION

Since 1992, the Promoting Financial Investments and Transfers (PROFIT) Project, sponsored by the U.S. Agency for International Development (USAID), has been exploring opportunities to expand the commercial sector provision of family planning services in developing countries. As education levels increase, demand for contraception rises and the population of reproductive age expands. Most developing countries will find it difficult to provide adequate supplies of contraceptive services through a system dependent exclusively on government or donor funding. If all contraceptive demands are to be met, it will be necessary to tap private sources for funding and to utilize private providers more extensively.

In most developing countries, the private sector already plays a major role in the curative care of minor illnesses. At least for the more prosperous members of the population, it should be possible to provide family planning services through nongovernmental providers who are paid by clients, employers, or health insurance programs.

PROFIT staff members have explored a wide variety of potential subprojects to expand commercial sector family planning. PROFIT has supported efforts to do this in nine countries, using such mechanisms as education and training about contraceptives for consumers and providers, loans for private health care providers, prepaid health plans that include family planing benefits, and commodity distribution.[1]

In analyzing possible subprojects, PROFIT carefully considered the regulatory environments in each host country. In some cases, this consideration was limited to the factors that would affect a specific, proposed subproject. In other cases, PROFIT undertook a more comprehensive regulatory assessment. Overall, these assessments have provided insights into how trade and regulatory barriers can affect the success of projects to expand commercial sector provision of family planning services.

[1]Brazil, El Salvador, India, Indonesia, Kenya, the Philippines, Romania, Russia, and Zimbabwe.

This report is meant to share some of the knowledge PROFIT has gained through its experiences in conducting regulatory assessments. It highlights the areas to explore when conducting such an analysis, building on the analytic structure developed by Genevieve Kenney of the Urban Institute,[2] and provides practical pointers for conducting regulatory assessments drawn from PROFIT's experiences, including possible sources for information and questions to ask these sources. Finally, the report discusses general strategies for applying the results of such an analysis.

PROFIT has conducted country assessments that explore the general political, economic, social, investment, and financial environments of a country as they relate to commercial sector family planning and the development of subprojects. PROFIT staff members also have carried out targeted assessments related to specific projects or approaches, including in Romania, Zimbabwe, and Vietnam.

PROFIT used the information it gathered about trade and regulatory barriers to design and implement family planning subprojects. For example, a secondary objective of some subprojects was to affect a policy barrier identified through the assessment (e.g., opening a dialogue among commercial sector firms and department of health officials to examine how to reduce such barriers). For other subprojects, eliminating barriers to commercial family planning was a primary objective (e.g., changing eliminate import taxes on contraceptive commodities or regulations that restrict health care professionals' abilities to provide family planning services). Most often, PROFIT used the regulatory assessments to creatively design subprojects to work successfully within a given regulatory environment. This report focuses on PROFIT's experiences in Romania, Zimbabwe, and Vietnam because the project's work in these three countries illustrates the role of the assessment framework, how to apply the framework in practice, and strategies for using assessment findings in project design.

[2]Genevieve Kenney, *Assessing Legal and Regulatory Reform in Family Planning.* Washington, DC: OPTIONS for Population Policy Project, The Futures Group, 1993.

2.0 A FRAMEWORK FOR ANALYZING THE REGULATORY ENVIRONMENT

Researching laws and regulations can be confusing, even in countries where such documents are well codified and readily available. The process gets more complicated when documents are published sporadically and are not translated into international languages. Because the way regulations are structured varies by country, it helps to have a general framework for conducting a regulatory analysis.

In proposing a generalized typology for family planning regulatory analysis, Kenney (1993: 8) identifies five categories of regulation in a checklist format:

- Regulations that constrain contraceptive options
- Tax and import policies
- Advertising and promotion regulations
- Other regulations affecting the commercial sector
- Restrictions affecting nonprofit organizations

PROFIT found Kenney's typology useful in organizing regulatory assessments. The left column in ***Table I*** shows Kenney's categories, and the right column lists potential sources for information on restrictions that might affect commercial family planning services, based on PROFIT's experience (The Appendix lists some useful questions to ask when interviewing each of these sources). If resources allow, more than one individual or organization should be consulted from each source grouping.

Table I.
Sources of Information by Regulatory Category

Legal and Regulatory Categories*	Source of Information
1. Regulations that Constrain Contraceptive Options < Restrictions on specific methods < Restrictions on service delivery and distribution < Registration, licensing, and certification policies < Limitations on private practice	C Drug licensing authority C Regulatory agencies licensing pharmacies C Agency licensing clinics and physicians C Drug manufacturers and importers C Drug wholesalers and distributors C Retail pharmacists and trade group C Physicians and physician groups C Nonphysician family planning providers C Nonprofit family planning clinics C Health insurers or social insurance agency
2. Tax and Import Policies	C Drug manufacturers and importers C Drug wholesalers and distributors C Retail pharmacists and trade group C Physicians and physician groups C Social marketing organizations
3. Advertising and Promotion Regulations < On prescription drugs < On family planning products < On point-of-purchase materials or mass media < On generic and brand advertising	C Regulatory agency C Drug licensing authority C Agencies licensing clinics and trade group C Drug manufacturers and importers C Drug wholesalers and distributors C Retail pharmacists and trade group C Physicians and physician groups C Nonphysician family planning providers C Nonprofit family planning clinics C Advertising agencies and advertisers C Social marketing organizations
4. Others Regulations Affecting Commercial Sector < Patent and trademark laws < Discouragement of foreign investment < Statutory price controls	C Drug manufacturers and importers C Drug wholesalers and distributors C Retail pharmacists and trade group C Physicians and physician groups C Nonprofit family planning clinics C Social marketing organizations
5. Restrictions affecting nonprofit organizations < On sale of donated commodities, < Use of fieldworkers, and < Fees charged for services	C Nonprofit family planning clinics C Social marketing organizations C Agencies licensing clinics & physician offices

Table I. Sources of Information by Regulatory Category	
Legal and Regulatory Categories*	**Source of Information**

Source: Genevieve Kenney, *Assessing Legal and Regulatory Reform in Family Planning.* Washington, DC: OPTIONS for Population Policy Project, The Futures Group, 1993.

3.0 PRACTICAL POINTERS FOR CONDUCTING REGULATORY ASSESSMENTS

What follows are practical tips for conducting a regulatory analysis derived from regulatory assessments conducted by PROFIT. In general, they reflect a common-sense approaches sharpened by practical experience.

3.1 Insist on getting texts of law and regulations and independent translations.

It is surprising how often a person being interviewed will describe the content of a regulation without having read it. Sometimes, the content described will reflect the individual's bias. Whenever a respondent refers to a regulation, ask for a copy, or at least a citation to the appropriate gazette, administrative circular, law, or other controlling document. Obtain this and have it translated independently. If the language seems inconsistent with statements in the interview, you may want to return and review the text with the respondent. Careful study of the text may suggest that the laws and regulations provide more or less flexibility than is exercised administratively. Where the goal is to increase options, ask the respondent if the apparent flexibility in the regulation can be used to expand the number of family planning providers or the services they offer. Ask why this flexibility has not been used.

3.2 Use consistent questions with flexible follow-up across all the sources interviewed.

Interviews must be designed to get consistent information, but the interviewer must respond promptly to statements that suggest inconsistencies or identify previously unrecognized requirements. We start with a list of questions (See Appendix A), and then try to cover all of these in the interview. In particular, when both regulator and regulated are being interviewed, be sure to cover the same topics with each.

3.3 Document interview notes promptly.

After two or three days of interviewing all of the parties in a regulatory system, it becomes difficult to remember who said what. When you start getting different interpretations, it can be difficult to go back to the various sources and try to resolve discrepancies. We found it necessary to document our interview notes every night. When the team split up to interview different parties, we could share our experiences through the notes. The notes then become the most important source as the team assembled recommendations and the final report.

3.4 Assess the impact of regulatory reform on providers based on the number and type of providers who would be affected by the changes.

The importance of a particular regulation depends on the number of providers who are subject to it. If there are few obstetrical specialists in a country, it is more important to see that regulations permit general practitioners to provide family planning services. Where there are a reasonable number of specialists, then it may be less important to encourage general practitioners as family planning providers.

However, it is difficult to get accurate estimates by locality of the number of service providers within a particular category. Registries or medical association membership lists, if they exist, are often out of date, as there is no standard updating procedure and licenses may be granted for life. A government ministry may have good information on the physicians employed in the public sector but no knowledge of the number who practice privately (instead of or in addition to practicing in the public sector). It may

be necessary to use two or three estimating techniques to get an idea of the number of private practitioners in a particular regulatory category.

An important issue can be the level of training required for provision of clinical methods (e.g., IUD, sterilization). Therefore, in addition to estimating the number of practitioners subject to each regulation, it is necessary to determine the average level of clinical education for each type of provider. For example, a desire to guarantee the highest possible level of quality for family planning services may make it necessary to focus first on improving clinical training for general practitioners and, only when the quality of their services have improved, encourage them to broaden their provision of clinical family planning services.

3.5 Determine the licensing standards used for nonprofit and nongovernmental organization clinics.

Regulatory policies can constrain the ability of nonprofit organizations to provide family planning services, because these organizations are generally held to the same licensing standards as for-profit clinics or pharmacies. Therefore, be sure to determine the licensing standards used for nonprofit clinics. Explore with the regulators the possibility of making exceptions to the regulations, or creating a special category of regulations, for well-funded and well-managed nonprofit clinics (e.g., nongovernmental organizations). For example, some countries permit a nonprofit clinic to perform certain procedures even when private clinics are restricted from offering the same services.

In Vietnam, for example, nongovernmental organizations (NGOs) are allowed to perform outpatient sterilizations which require highly trained personnel while the government is still reluctant to allow even relatively less complex IUD insertions in private clinics. Although these clinical services can be provided by private obstetricians and midwives with the approval of Provincial health authorities, such approvals are not now being granted.

It is also important to determine whether nonprofit organizations are treated differently from other clinics under laws that govern corporate formation or taxation. Is a surplus of revenues over expenses earned by a nonprofit subject to taxation? If so, this will limit the nonprofit's ability to expand its services using surpluses earned from existing operations. In some countries, it may be very difficult to form a nonprofit organization that provides health services.

3.6 Search for and understand the ramifications of unwritten, informal regulations.

Even in the United States, not every criterion used in establishing regulatory compliance is catalogued or published. For this reason, it is important to learn as much as possible about the standards *actually used* in making inspections. If possible, accompany an inspector, or look at reports citing regulatory violations. What constitutes an unacceptable level of hygiene or adequate space? It is not necessary to suggest that some different standard be enshrined in law, but it may be helpful to encourage the country to analyze the costs and benefits of such de facto standards and to examine whether a more lenient alternative standard would provide an acceptable level of quality. If, as in many countries, the discretion left to inspectors is an invitation to corruption, then it may be necessary to consider including a revised and reasonable standard in written regulations.

3.7 Consider the commercial needs of the private sector as you analyze regulations.

Attempts to craft regulations to respect the economics of commercial practice can have a positive effect on the provider's willingness to expand family planning services. Therefore, it is important to understand the economic forces that drive the commercial sector and to suggest reforms that are consistent with these economic forces. For example, in Romania PROFIT found that the state health department's delays in paying pharmacies for prescription drugs created a cash-flow crunch for pharmacists. Contraceptives do not require a prescription and are not covered by the insurance available to most Romanians. Thus, contraceptive sales and direct payment from users can help create cash flow for the pharmacist. A strategy that reinforced this self-interest showed potential for expanding the distribution of contraceptives through pharmacies.

Public sector regulators do not necessarily consider the economics of commercial practice. Often, a regulation may cause a major increase in cost or a decrease in the supply of services with only marginal benefits to quality. For example, regulations may require long training programs for those who seek certification as a family planning provider. Such programs may be feasible for a public sector physician on training leave, but not for a commercial sector physician for whom time is money. Thus, a reasonable

target for regulatory reform would be to adjust the training requirements so that they could be met with courses offered in the evenings or on weekends, or to grant certification after an applicant passes a competency exam.

3.8 Understand the ramifications of tax and trade barriers at the retail level.

Importers and distributors are usually well-versed in current tax and trade issues and are accessible sources of information. In a limited number of countries, foreign exchange controls may be the most important single barrier to contraceptive imports. Any study must determine the current, as well as the historic, effect of such barriers. In Romania, we found that exchange controls had been a major barrier. Shortly before the study, this barrier was removed and currencies became freely convertible. However, rapidly depreciating exchange rates — combined with retail price controls — continued to discourage importing commodities because importers were concerned that they could not recapture the initial foreign exchange cost at regulated local currency prices. A regulatory assessment must be careful to take into account price controls (listed by Kenney under "other regulations" affecting the commercial sector) as well as the effect of foreign exchange.

3.9 Identify hidden advertising and promotion regulations.

Advertising and promotion regulations are often not well documented or stipulated, unlike requirements for drug registration or provider certification. For example, in authoritarian countries, the government may have unwritten policies about advertising or program content. The acceptability of different images or phrases will vary depending on the biases of the editors or publishers. Media owned by the state may be subject to restrictions that are not always explicit. Even private media outlets may have de facto policies about sensitive subjects such as contraception which reflect the positions of the owners, advertisers, or readers. The best way to identify these unwritten policies is to talk to advertisers and advertising agencies about problems they have experienced in placing advertisements or developing public relations materials. In Vietnam, a social marketing agency selling condoms showed the study team advertisements that had been accepted by the national media and those that have been rejected, thereby revealing some of the problems PROFIT could expect to encounter in advertising.

3.10 Seek information from multiple perspectives.

Lawyers struggle to write definitive documents proscribing or prescribing conduct by the commercial sector, but in the real world, application of these statutes and regulations may be less clear-cut. For example, laws may be written, but the implementing regulations may never be issued or may be enforced only sporadically. Even where regulatory language appears explicit, there is often substantial room for administrative interpretation. It is important to understand the *real* regulatory climate — what individuals or companies in the commodity production/distribution chain or in the provision of family planning services experience.

The process of triangulating the real regulatory world involves researching the appropriate documents and talking to the regulators and the regulated. While drug registration and import rules are set at the national level, rules that affect medical providers and pharmacies are usually implemented at the provincial or local level, even in nations with a relatively strong centralized government. It is therefore important to interview regulators at all levels, as well as individual providers or provider organizations.

3.11 Factor family planning survey data into the regulatory analysis.

Review the most recent surveys of family planning practices, including the DHS (Demographic and Health Survey). These data should not only show the level of contraceptive knowledge and prevalence but also the current sources for contraceptive users. Below are three cases from PROFIT's experience when the study of family planning data, combined with the regulatory analysis, suggested an agenda for action.

3.11.1 Case 1: Romania

In some cases statistics indicate a trend that can be reinforced with a commercial sector strategy. For example, in Romania, the number of reported abortions peaked in the first year after the fall of the communist regime, when abortion became legal, but then the number of abortions began to decline. The number of reported abortions dropped 41 percent in three years, from 992,000 in 1990 to 586,000 in 1993, according to data from the Romanian Ministry of Health, although the birth rate did not rise ***(see***

Table II). Interestingly, the data showed that use of modern contraceptive methods was low (less than 10 percent).

Allowing for statistical aberrations, the data on abortions and live births suggest that some women may have begun to shift to using more effective contraceptives methods, most likely obtained from private sources. The data indicate that the stage has been set to build on a trend begun on the individual level, to substantially expand the use of modern contraceptives.

Table II.
Sources of Contraception in Romania

Women Using Modern Method: By Method and Source	% of Total	% Obtained from Public Sources	% Obtained from Private Sources*
Pill	2.3	0.7	2.7
Condom	3.5	1.1	3.9
IUD	2.5	1.7	1.6
Female sterilization	1.0	1.0	–
Injectable	–	–	–
Male sterilization	–	–	–
Total:	9.3	4.5	8.2
Percent of Women Using Traditional Contraception	30.5	–	–
Percent of Women Not Using Contraception	60.2	–	–

* Row totals may not add up because data come from different sources
Sources: Private: unpublished data from Ministry of Health for 1990–1993, Bucharest; other: Institute for Mother and Child Care, Romania (IMCC), *1994 Reproductive Health Survey.*

The trend toward increased modern contraceptive use can be reinforced through educational campaigns that use mass media and by improving the availability of modern methods at private sector pharmacies. This approach is promising because prescriptions are not required for oral contraceptives in Romania and most pharmacies are private.

Another strategy might be involve attempting to change the regulations that govern physicians' practices so that more family planning advice could be provided by private sector physicians. Existing laws require that private practitioners undertake substantial postgraduate training before they can provide family planning services (six weeks for OB/GYNs and six months for general practitioners). However, changing regulations or licensing requirements is a slow and politically difficult process. Even if the regulations were liberalized, it seems unlikely that most Romanian obstetricians, who profit from the large number of abortions they perform, would change their traditional opposition to hormonal contraceptives. Using pharmacies to sell supply-based methods to young women promises to be a quicker approach.

3.11.2 Case 2: Vietnam

Even a socialist country like Vietnam may have a well-developed commercial sector capable of providing family planning services or supplies, as illustrated by data from a 1994 survey.[3] Current patterns of method use and sourcing help to identify opportunities to expand the commercial sector role in delivering family planning services as well as areas where regulatory efforts may have a major impact. As shown in Table III, in Vietnam, the IUD and female sterilization are the most prevalent forms of family planning, and high abortion rates[4] indicate that abortion significantly contributes to efforts to limit family size. These invasive procedures, which require substantial clinical training for providers and good-quality facilities, are only provided by the private sector on a marginal basis. This is due to the fact that governmental health officials are unwilling to approve the provision of these services in private offices. As a result, efforts to shift the provision of clinical methods from the public to the commercial sector would require both regulatory reform and efforts to improve the quality of care. Regulatory reform is needed to establish guidelines under which commercial practitioners could provide clinical procedures, and the private providers need to have the proper training, facilities, and equipment to provide the favored methods, which could be supported with training programs and loans for equipment.

[3]N. Van Phai, ed., *Major Findings: Vietnam Intercensal Demographic Survey: 1994.* Hanoi: Statistical Publishing House, 1995.

[4]Abortion data are not reflected in the contraceptive use tables. However, other IDS data suggest that at least 13 percent of women have had such a procedure (Van Phai, 1995).

Table III.
Sources of Contraception in Vietnam

Women Using Modern Method: By Method and Source	% of Total	% Obtained from Public Sources	% Obtained from Private Sources
Pill	2.0	1.0	1.0
Condom	4.0	2.0	2.0
IUD	33.4	31.7	1.7
Female sterilization	0.2	0.1	0.1
Injectable	0.2	0.2	–
Male sterilization	4.0	4.0	–
Total:	44.0	39.0	4.8
Percent of Women Using Traditional Contraception	21.0	–	–
Percent of Women Not Using Contraception	35.0	–	–

Source: N. Van Phai, ed., *Major Findings: Vietnam Intercensal Demographic Survey: 1994.* Hanoi: Statistical Publishing House, 1995, pp. 58, 65.

On the other hand, approximately half of supply-based methods (i.e., condoms and pills) are provided by the private sector. This reflects the fact that a substantial number of physicians in Vietnam are in private practice and that Vietnam has a strong private retail pharmaceutical sector. While these methods currently reach only 14 percent of modern contraceptive users, there appears to be the infrastructure (i.e., drug wholesalers and retailers) to accommodate many more private clients. In addition, regulatory analysis showed that licensing requirements for pharmacies are minimal and often not enforced. As a result, expanding commercial sector provision of these supply-based methods was identified as a relatively easy strategy to pursue given Vietnam's current regulatory environment.

3.11.3 Case 3: Zimbabwe

In Zimbabwe the government still dominates provision of family planning. Contraceptive pills are the leading method, used by nearly 80 percent of women who use a modern contraceptive method. Pills are primarily provided through the public sector. During interviews, pharmaceutical distributors and pharmacists agreed that the ready availability of subsidized pills in the public sector makes it difficult to establish a commercial market. In this case, for a commercial sector strategy to succeed, it would be essential to work toward policy reform that would enable public sector services to be targeted to those who cannot afford an alternative while encouraging those who can afford to pay for services to utilize commercial services.

In addition, the provision of clinical methods needs to be expanded. Interviews with private doctors indicate their interest in providing clinical methods, yet their ability to do so is limited by lack of training and equipment.

The limited supply of trained physicians also indicates a need for provision of private family planning services by nonphysician providers such as midwives. However the law that governs private midwives limits their ability to provide services by requiring that they be directly supervised by a physician and preventing them from dispensing or prescribing medication, including oral contraceptives.

As a result, in Zimbabwe, the main component of PROFIT's strategy were to focus on resolving problems with the quality of private family planning services. PROFIT worked with those private providers who were already permitted to provide services (doctors and pharmacists), while working towards longer-term policy reform that included coordinating with the public sector on the provision of contraceptives and working to change the regulations regarding midwives' ability to provide family planning services. Additionally, an information, education, and communications (IEC) campaign was organized to motivate consumers to seek family planning services from the private sector.

Table IV.
Sources of Contraception in Zimbabwe

Women Using Modern Method: By Method and Source	% of Total	% Obtained from Public Sources	% Obtained from Private Sources	n
Pill	33.1	29.1	3.7	1,449
Condom	2.3	1.5	0.7	149
IUD	1.0	0.7	0.3	38
Female sterilization	3.2	2.7	0.5	149
Injectable	2.3	1.8	0.4	149
Male sterilization	0.2	–	–	109
Total:	41.1	35.9	5.9	2043
Percent of Women Using Traditional Contraception	6.0	–	–	_
Percent of Women Not Using Contraception	51.8	–	–	_

Source: Zimbabwe Demographic and Health Survey. Calverton, MD: Macro International, 1994.

4.0 A QUESTION OF STRATEGY

The PROFIT experience suggests that four general strategies can arise from a regulatory analysis. The strategy to follow depends on the barriers identified and on the likelihood of developing an effective coalition to change an existing barrier.

4.1 Strategy One: Work within the existing regulatory climate

This is the general strategy PROFIT followed in Zimbabwe. In its assessment of the private medical sector in Zimbabwe (Adamchak, 1996), PROFIT found that perceived restrictions on establishing private practices prevents many nurse/midwives from doing so. In fact, there are no legal restrictions on nurse/midwives having private practices. Nonetheless, it remains difficult for them to establish practices because regulations prohibit independent nurse/midwives from prescribing or dispensing most drugs and because standard insurance practices do not generally reimburse nurse/midwives for their services.

Working within this setting, PROFIT sought to expanding nurse/midwives' ability to establish private practices, while linking these providers with physicians who are able to prescribe and dispense family planning methods and receive reimbursement on behalf of the nurse/midwives. By working within the existing regulatory climate, PROFIT expanded the nurse/midwives' ability to provide family planning services.

4.2 Strategy Two: Modify ways in which regulations are implemented

Some countries display a neutral or positive official attitude towards commercial sector family planning at the same time that the requirements imposed by government create significant obstacles to commercial sector expansion. In Vietnam, PROFIT found that regulations nominally permit obstetricians and midwives to provide clinical family planning services such as IUD insertion, but that general practitioners are not authorized to provide clinical services. With a reasonable number of trained midwives and obstetricians available, PROFIT sought to work within the existing regulatory

framework to get more of these professionals to provide family planning services in the commercial sector, rather than to fight to include general practitioners in the category of authorized providers.

In Vietnam, the establishment of facilities where clinical services (i.e., IUD insertions) might be performed by obstetricians or midwives is subject to the approval of the Provincial Health Department. However, since there are no standards for such approval and since approval is rarely granted, PROFIT identified three critical steps that must be taken to modify the way the regulation is implemented:

- Define realistic standards which providers can afford to meet.
- Educate both the implementers of the standards and the affected providers about the new standards. Those who implement the standards should fully understand the standards and the procedures for applying them. Providers should understand what is expected of them and what procedures they must follow in order to get approval.
- Identify sources of assistance for providers to comply with the standards. This could include making loans to providers to enable them to meet the standards.

4.3 Strategy Three: Exploit loopholes and avoid hostile regulatory sectors

In some countries, regulatory barriers may be supported by entrenched interests that would be difficult to move. In Romania, PROFIT found that a conservative coalition of obstetricians strongly opposed easing the requirements that have restricted the availability of modern family planning services by physicians. Most of these obstetricians had been trained during the Communist regime[5] and had little knowledge of modern hormonal contraceptives. In addition, they often profited from providing abortions. These interests opposed any change in a requirement that called for six months of special training — on top of internal medicine or obstetrical qualifications — before a physician could provide family planning services.

[5]The Ceausescu Regime was in power from 1969 to 1989, during which time family planning was banned and negative information about hormonal methods was widely disseminated. This ban was lifted in 1989.

On the other hand, Romanian law permits pharmacists to dispense oral contraceptives without a prescription. Pharmacies in Romania have been privatized and are generally run by well-educated pharmacists. Many of these pharmacists are women. Because of delays in payment for state subsidized prescription drugs, the pharmacists have an incentive to sell products such as oral contraceptives for cash. Barriers to registration and importation of oral contraceptives are acceptably low, with a number of products already registered. The media are generally open to advertising and public relations messages about contraception. Rather than take on opposition from obstetricians within the Ministry of Health, PROFIT suggested basing a strategy on commercial pharmacies and providing pharmacists with more education so that they could advise their clients. Simultaneously, PROFIT used the mass media to spread the word that safe and effective alternatives to abortion were available to those who want to limit family size. Elements of the regulatory climate that were favorable to commercial sector family planning initiatives are thus exploited without attempting to change unfavorable regulations.

4.4 Strategy Four: Change the law or regulation

This is often a difficult path to take. Building a coalition to support a change in regulation, then implementing a change, can take many years. The process also can make enemies who will block other, easier approaches to expanding the private sector. Planners should consider whether the benefits of the regulatory change can be achieved within a project's lifetime. Occasionally, a clear and simple objective can yield results. For example, in Zimbabwe, changing import duty laws on contraceptive commodities may be easier than changing restrictions on midwives' ability to dispense prescription medications; however, each effort requires working with different regulatory bodies. Changing import duty laws requires lobbying government ministries; changing regulations affecting midwives' ability to dispense prescription medication involves taking into consideration the safety of clients and dealing with the Health Professions Council, which sets these regulations. Since the concept of changing midwives' clinic practices is a very new one in Zimbabwe, a great deal more groundwork may be required, which argues for trying to change import duties.

In fact, while exploring the feasibility of local condom testing and packaging in Zimbabwe,[6] PROFIT found that, through lobbying efforts, import taxes had been removed for condoms but still existed for

[6] S. Mitchell, L. Elam, and C. Connor, *Local condom testing and packaging in Zimbabwe: A Cost Analysis,* Arlington, VA: PROFIT Project, 1993.

oral contraceptives. More recently, efforts to lobby the Ministries of Justice, Legal and Parliamentary Affairs, and Finance resulted in the reduction of import duties on contraceptive products from 5–10 percent, which facilitates the sale of affordable contraceptive products through the commercial sector.

5.0 CONCLUSIONS

While regulatory reform will be an important component in a strategy to increase commercial sector delivery of family planning services in many countries, there is no single strategy that will work in every country. A thorough regulatory analysis can help suggest an appropriate strategy, particularly if it takes into consideration the practical pointers presented in this report. PROFIT's experience indicates that the following three facets are particularly critical to conducting this type of analysis.

- Develop a clear understanding of what existing regulations say, and what they do not. The conventional wisdom does not necessarily reflect what is in the statute book or the official gazette.
- Look beyond the laws to understand how regulations are actually implemented and practiced. In Zimbabwe and Vietnam, statutory authority to license private providers to provide family planning services may not be exercised by the responsible officials. De facto standards may have developed which make it impossible or prohibitively expensive for a provider to obtain the license which is theoretically available.
- Carefully study the existing pattern of contraceptive provision and use and relate this to the regulatory environment. Eliminating a regulation may have little effect on contraceptive prevalence or commercial purchase if the new freedom to provide contraceptive services is at odds with the country's existing practices.

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Appendix: Key Questions for Interviewers

Drug licensing authority

- How many contraceptive drugs are currently approved? How many have been approved in the last year, the last two years, the last five years? What applications are pending?
- What weight is given to existing drug registrations in other countries? To safety and efficacy studies performed for other countries?
- How long does it normally take to approve a new drug?
- What are the costs of obtaining a license for a new drug?
- What are the rules for testing of regular shipments of domestically manufactured or imported drugs? What laboratories are qualified to do the testing, and what is the cost?
- (In countries where contraceptives are manufactured) What are the rules for production facilities? (If written, obtain and compare with good manufacturing practices). How frequent are inspections of manufacturing facilities? What is the training of the inspectors?
- If possible, try to follow the approval process for a contraceptive product licensed in the last two years. Check the story from the regulators against the story told by the manufacturer or importer.
- What labeling and package insert requirements apply to contraceptives?

Regulatory agency responsible for licensing pharmacies

- What are the regulations governing establishment of a pharmacy? Who can establish? Is there any "determination of need" for a facility in a particular area? Is there a standard (x pharmacies per 10,000 population) which is used in determining need?
- What are the requirements for the physical facility? For record keeping? For the training and experience of the owner? For the training and experience of the staff?
- If there are different regulations for different classes of drugs, in what category do various contraceptives fall? Are contraceptives subject to the same record keeping requirements as narcotics?

- What classes of contraceptives require a prescription?
- Are there any regulations which govern the display of information concerning contraceptives?
- What price control regulations apply to retail pharmacies? Determine the price control formula which applies at the retail level.

Agencies licensing clinics and physicians' offices

- How are offices categorized (by specialty, etc.)? Are there any restrictions on what a practitioner can do once s/he is licensed (license by specialty, special licenses for certain procedures such as IUD insertion, abortion/menstrual regulation, etc.)?
- What services are permitted for each category of license?
- What are the prerequisites for a license in each category? Training? Physical facilities?
- Must the provider have special training to offer certain family planning services? What is this training? Who offers the training? How long is the course? How often is the course given? Are there any requirements for periodic retraining (Continuing Medical Education)?
- What operational requirements apply to a licensed office or clinic in each category? Records? Staffing?
- What approvals are required to start an office or clinic? Are there any capacity controls ("Certificate of Need")? If there are capacity controls, what standards are used to determine need?
- Who approves initial licenses? How much discretion do they have? How long does the license approval process take?
- Are physicians' offices subject to periodic inspection? For what requirements? Are clinics subject to periodic inspection? For what requirements? How often?
- What is done when an office or clinic fails an inspection? What sanctions are imposed? Ask for an example of a recent enforcement action?
- What prescription requirements apply? Do these apply to contraceptives? Can the physician or clinic dispense family planning supplies (check by category — oral contraceptives, IUD, etc.)?
- Must a physician employed by the Government obtain approval to establish a private practice? Who grants this approval? What criteria are used in granting the approval for private practice? Can the practice be conducted in government facilities? Are such practices subject to regular inspection in any way?

Drug manufacturers and importers

- Follow the story of licensing of a new product from the manufacturer's or importer's point of view.
- What good manufacturing practices apply to domestic production? How does the inspection process work for manufacturing? How well trained are the inspectors? What is the level of bribery/corruption?
- What is the process for monitoring safety and efficacy of imported product? What are the sampling requirements? Is the cost of testing significant? Who performs the tests, and how competent is the testing agency?
- Do foreign exchange controls inhibit the import of contraceptives or manufacturing inputs? How hard is it to obtain the necessary foreign exchange? Is the degree of difficulty the same as that for other drugs?
- What quotas or tariffs apply to contraceptive products? (Compare to international norms) Does it make any difference who is the end user of the product (e.g., are contraceptive products free of duty for government or a nonprofit, but not for commercial sale)?
- Are there delays or leakages in the import process? Does any of this occur in the name of official quality or customs inspections?

Drug wholesalers and distributors

- Do price controls apply at the wholesale or retail level? Determine the exact method for determining allowable prices. What kind of profit margin does this leave at each level of the distribution chain?
- How does the price control system respond to inflation in import or manufacturing prices? Does this deter import or production?
- What regulations apply to warehousing? Does this have any impact on product cost? How are these regulations enforced?
- Are there any restrictions on the marketing activities of the distributors?
- Are there limitations on where contraceptives can be distributed? Can some methods be distributed beyond the pharmacy? If so, which methods?

Retail pharmacists and their trade group

- How difficult is it to establish a new pharmacy? What problems do the prospective pharmacy operator encounter?
- How are pharmacy regulations enforced? How often is a facility inspected? What deficiencies are cited frequently? What happens when a deficiency is cited (fine, opportunity to correct, bribe to inspector)?
- Are there overlapping regulatory requirements between health and municipal agencies? How do these effect the cost of running a pharmacy?
- Do price control regulations apply? How are these regulations enforced? What effect do price control regulations have on profitability?
- Does the pharmacy have cash flow problems? If so, why?
- What contraceptive products are covered under national health insurance (if relevant)? What products are sold for cash?
- How much knowledge do pharmacists have about modern contraception? Do they feel comfortable counselling patients? Do they have informational materials available for distribution to interested customers?
- Does the pharmacy association have any input into regulations? What changes in regulation do they currently advocate?
- Does the pharmacy association advocate a limit on the number of licensed pharmacies? Do they advocate a crackdown on drug sellers not licensed as pharmacies?

Physicians and physician groups

- What problems do physicians encounter in establishing private practices? Which agencies must provide approvals? What barriers are most prevalent and difficult to overcome? What regulation is cited by a government agency in throwing up these barriers? How do physicians get around the barrier (if they do)?
- What regulatory standards are the most costly? Ask for a citation to the applicable regulation.
- How often (if at all) is the private office or clinic inspected? By what official? Does this vary with the type of practice?
- What happens when the office/clinic is cited for regulatory violations? How are these violations resolved?

- What regulations apply to prescribing of contraceptives? To the dispensing of contraceptives (be specific by product type)? Do physicians see limitations on dispensing as a problem in patient care? In achieving profitability?
- Are there restrictions which limit the types of contraceptives physicians can prescribe or the types of physicians who can prescribe certain methods?
- What limitations do physicians find to expanding the provision of family planning services?

Nonphysician family planning providers (midwives)

- Is this group allowed to provide family planning services in private offices? Which services? What requirements for supervision by physicians or others apply?
- Can these practitioners provide family planning services if employed by a physician? What type of license must the physician have to employ this professional to provide family planning services? Obtain citation to the regulation, and the applicable standards.
- Must the provider have special training to offer certain family planning services? What is this training? Who offers the training? How long is the course? How often is the course given? Can private practitioners enroll in this course? At what cost? Are periodic training updates required?
- Can the provider dispense any family planning supplies? Which ones? Do any limitations on dispensing affect the viability of a private practice?

Nonprofit family planning clinics

- Do regular clinic or physicians office regulations apply to the organization? Are there any restrictions on the type of organization which can obtain a clinic license?
- What problems were encountered in obtaining initial approvals for the clinic? Is any "Determination of Need" required? What standards are use to determine need? At what level in the health bureaucracy are decisions concerning the license application made?
- Are waivers of generally applicable regulations required for any family planning services offered by a clinic? (For example, performing sterilizations or abortions?) How are these waivers obtained? If waivers have been granted, try to get a case history. Are there licenses or approvals, in addition to licensing by the health Authority, which must be obtained by a clinic? Municipal approvals? Building approvals? How difficult is it to obtain such approvals?

- Is the clinic subject to regular inspection? By what agencies? What requirements are enforced? What criteria are used for compliance?
- Has a clinic ever been subject to a regulatory enforcement action? For what violation? How was the situation resolved?
- What tax rules apply to the nonprofit clinic? Do these rules make it difficult to use any operating surplus for service expansion or enhancement?
- If the NGO has an international affiliation, did this help or hinder the establishment of the clinic? Is the affiliate's investment in the clinic subject to general controls on foreign investment? What are these controls?

Advertising agencies and advertisers

- Are there any formal regulations limiting the content of advertisements for family planning services? What agency or organization approves advertising content?
- Has the advertiser submitted advertisements for family planing or similar services? What is the response, by media type or media outlet?
- Ask the advertiser to describe advertisements that were submitted and the changes that were required.

Social marketing organizations

- Do health officials seek to affect the content of information or advertising distributed by the organization? Does this involvement restrict the marketer's freedom of action?
- Are media outlets (print, radio, TV) open to the marketer? Under what conditions? What content restrictions have been applied to advertising messages?
- Does the organization send sales personnel to pharmacists? To doctors? To midwives? What is the practitioner's level of knowledge about the product prior to the sales contact? Do pharmacists or practitioners distribute to patients informational materials provided by the marketer?
- Do import tariffs or exchange rate controls affect the supply of product, or its costs? By how much?

- Do maximum or minimum price regulations apply to the sale of the product? Do these create an economic problem?
- Are there limitations on where contraceptives can be distributed via social marketing? Can some methods be distributed beyond the pharmacy? If so, which methods?

Health insurers or social insurance agency (if either pays for significant amounts of outpatient care)

- Are there regulations mandating certain benefits? Do these mandated benefits include maternity care? Family planning services? If so, what services are mandated?
- Can any family planning services be billed to the insurer as part of an obstetrical or gyn services? If so, what services can be billed?
- Must the insurer cover all willing providers or does it restrict the number of practitioners with contracts? Does the insurer have any right to limit the number of practitioners in a specific category or region which can receive insurance reimbursement?
- What categories of practitioner have a right to bill the insurers? (For example, can an obstetrician, but not a general practitioner, bill for a family planning service? Can midwives bill for any services?)